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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SCHLAPKOHL, WALTER	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,761	ERLANDER ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	uaj

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 45-48, drawn to an array of polynucleotide probes capable of hybridizing to **one or one combination** of nucleic acid genes from Table 2 or 3, classified in class 435, subclass 287.2.

II. Claims 7-11, 14-19, 22, 32-35, 38-43 and 49-50, drawn to a method to determine survival outcome/prognosis if treated with tamoxifen, wherein the determination is made by detection of nucleic acids and as the claims read on ***one or one combination*** of genes selected from Table 2 or 3, HOXB13, IL13BR, CACNA1D, and SEQ ID NOS: 8-37, classified in class 435, subclass 6.

III. Claims 7-11, 14-19, 22, 32-35, 38-43 and 49-50, drawn to a method to determine survival outcome/prognosis if treated with a selective estrogen receptor modulator (SERM), wherein the determination is made by detection of nucleic acids and as the claims read on ***one or one combination*** of genes selected from Table 2 or 3,

HOXB13, IL13BR, CACNA1D, and SEQ ID NOS: 8-37, classified in class 435, subclass 6.

IV. Claims 7-11, 14-19, 22, 32-35, 38-43 and 49-50, drawn to a method to determine survival outcome/prognosis if treated with a selective estrogen receptor downregulator (SERD), wherein the determination is made by detection of nucleic acids and as the claims read on ***one or one combination*** of genes selected from Table 2 or 3, HOXB13, IL13BR, CACNA1D, and SEQ ID NOS: 8-37, classified in class 435, subclass 6.

V. Claims 7-11, 14-19, 22, 32-35, 38-43 and 49-50, drawn to a method to determine survival outcome/prognosis if treated with aromatase inhibitor (AI), wherein the determination is made by detection of nucleic acids and as the claims read on ***one or one combination*** of genes selected from Table 2 or 3, HOXB13, IL13BR, CACNA1D, and SEQ ID NOS: 8-37, classified in class 435, subclass 6.

VI. Claims 7-9, 12-13, 14-17, 20-22, 32-34, 36-41, drawn to a method to determine survival outcome/prognosis if treated with tamoxifen, wherein the determination is made by detection of proteins and or protein fragments and as the claims read on ***one or one combination*** of

genes selected from Table 2 or 3, HOXB13, IL13BR, and CACNA1D, classified in class 435, subclass 7.1.

VII. Claims 7-9, 12-13, 14-17, 20-22, 32-34, 36-41, drawn to a method to determine survival outcome/prognosis if treated with a selective estrogen receptor modulator (SERM), wherein the determination is made by detection of proteins and or protein fragments and as the claims read on ***one or one combination*** of genes selected from Table 2 or 3, HOXB13, IL13BR, and CACNA1D, classified in class 435, subclass 7.1.

VIII. Claims 7-9, 12-13, 14-17, 20-22, 32-34, 36-41, drawn to a method to determine survival outcome/prognosis if treated with a selective estrogen receptor downregulator (SERD), wherein the determination is made by detection of proteins and or protein fragments and as the claims read on ***one or one combination*** of genes selected from Table 2 or 3, HOXB13, IL13BR, and CACNA1D, classified in class 435, subclass 7.1.

IX. Claims 7-9, 12-13, 14-17, 20-22, 32-34, 36-41, drawn to a method to determine survival outcome/prognosis if treated with aromatase inhibitor (AI), wherein the determination is made by detection of proteins and or protein fragments and as the claims read on ***one or one***

combination of genes selected from Table 2 or 3, HOXB13, IL13BR, and CACNA1D, classified in class 435, subclass 7.1.

X. Claims 24-28 and 31, drawn to a method to determine therapeutic treatment based upon a patient's expected response to tamoxifen, wherein the determination is made by detection of nucleic acids and as the claims read on ***one or one combination*** of genes selected from Table 2 or 3, classified in class 435, subclass 6.

XI. Claims 24-28 and 31, drawn to a method to determine therapeutic treatment based upon a patient's expected response to SERM, wherein the determination is made by detection of nucleic acids and as the claims read on ***one or one combination*** of genes selected from Table 2 or 3, classified in class 435, subclass 6.

XII. Claims 24-28 and 31, drawn to a method to determine therapeutic treatment based upon a patient's expected response to SERD, wherein the determination is made by detection of nucleic acids and as the claims read on ***one or one combination*** of genes selected from Table 2 or 3, classified in class 435, subclass 6.

XIII. Claims 24-28 and 31, drawn to a method to determine therapeutic treatment based upon a patient's expected

response to AI, wherein the determination is made by detection of nucleic acids and as the claims read on ***one or one combination*** of genes selected from Table 2 or 3, classified in class 435, subclass 6.

XIV. Claims 24-26 and 29-31, drawn to a method to determine therapeutic treatment based upon a patient's expected response to tamoxifen, wherein the determination is made by detection of proteins or protein fragments and as the claims read on ***one or one combination*** of genes selected from Table 2 or 3, classified in class 435, subclass 7.1.

XV. Claims 24-26 and 29-31, drawn to a method to determine therapeutic treatment based upon a patient's expected response to SERM, wherein the determination is made by detection of proteins or protein fragments and as the claims read on ***one or one combination*** of genes selected from Table 2 or 3, classified in class 435, subclass 7.1.

XVI. Claims 24-26 and 29-31, drawn to a method to determine therapeutic treatment based upon a patient's expected response to SERD, wherein the determination is made by detection of proteins or protein fragments and as the claims read on ***one or one combination*** of genes

selected from Table 2 or 3, classified in class 435, subclass 7.1.

XVII. Claims 24-26 and 29-31, drawn to a method to determine therapeutic treatment based upon a patient's expected response to AI, wherein the determination is made by detection of proteins or protein fragments and as the claims read on ***one or one combination*** of genes selected from Table 2 or 3, classified in class 435, subclass 7.1.

Note: Claim 51 is incomplete and does not comprise any active method steps. As a result, Claim 51 has not be placed into any of the above groups.

The inventions are distinct, each from the other, for the following reasons:

Groups I-XVII are comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different polynucleotides/polypeptides which do not render each other obvious and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one

specific polynucleotide/polypeptide combination to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the polynucleotides/polypeptides are different and distinct and thus the methods drawn to different and distinct polynucleotides/polypeptides are different and distinct inventions from each other.

Note: the non-standard format of this restriction, separating the inventions into multi-invention groups drawn to independent or distinct combinations of polynucleotides and polypeptides, followed by an election of a single invention drawn to one combination of polynucleotides or polypeptides within the elected multi-invention group, was done for the sake of compactness of the communication and clarity, instead of using the more standard format setting forth each separate invention drawn to each separate sequence which would require a much longer communication.

For related process inventions, the inventions are distinct if (a) the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; (b) the inventions as claimed are not obvious variants; and (c) the inventions as claimed are either not capable of use together or can have a materially different

design, mode of operation, function or effect. See MPEP § 802.01. The methods of Groups II-V & X-XIII and VI-IX & XIV-XVII do not overlap in scope because the Group II-V & X-XIII inventions comprise detecting nucleic acids with, e.g., the use of quantitative PCR, whereas the Group VI-IX & XIV-XVII inventions comprise detecting proteins or protein fragments using any means. Furthermore, the Group II-V & X-XIII and the Group VI-IX & XIV-XVII inventions have a materially different design, mode of operation and/or effect since they comprise measurements of expression levels of products which are chemically and structurally different: nucleic acid levels (Groups II-V & X-XIII) and proteins (Groups VI-IX & XIV-XVII). Moreover the Group II-V & X-XIII and the Group VI-IX & XIV-XVII inventions are not obvious variants because, for example, the detection of a protein from a sample as in Groups VI-IX & XIV-XVII is not an obvious variation over the amplification of copies of a nucleic acid as in Group II-V & X-XIII inventions.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in

the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

For related process inventions, the inventions are distinct if (a) the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; (b) the inventions as claimed are not obvious variants; and (c) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function or effect. See MPEP § 802.01. The methods of Groups II-IX and Groups X-XVII do not overlap in scope because the Group II-IX inventions comprise *determining survival outcome/prognosis* of a subject with breast cancer treated with tamoxifen or other antiestrogen agent, whereas the Group X-XVII inventions comprise *determining a therapeutic treatment* based upon a patient's expected response to a tamoxifen or other antiestrogen agent. Furthermore, the Group II-IX and Group X-XVII inventions have a materially different design, mode of operation and/or effect since they result in entirely different outcomes: a prognosis (Groups II-

IX) and a therapeutic treatment (Groups X-XVII). Moreover the Group II-IX and Group X-XVII inventions are not obvious variants because, for example, the determination of a prognosis/survival outcome as in Groups II-IX is not an obvious variation over the determination of a therapeutic treatment as in Groups X-XVII.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions II-XVII and Invention I are related as processes and product for their practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the processes as claimed can be practiced by utilizing an array comprising any of the polynucleotide probes capable of hybridizing to the any of the myriad number of

combination of genes from Tables 2 or 3. For example, the Group II invention could be practiced by assaying with an array comprising the first two genes listed, e.g., in Table 2 or with the first two genes listed, e.g., in Table 3. Similarly, the Group XVII invention could be practiced by assaying for proteins with an array comprising polypeptides encoded by the first two genes listed, e.g., in Table 2 or by the first two genes listed, e.g., in Table 3.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Claim 6 links inventions II-IX and claim 23 links inventions X-XVII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 6 and 23. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d

1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be

traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view

the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

May 29, 2006

NANCY VOGEL
PRIMARY EXAMINER